

## **REMARKS**

### **The Amendments**

The claims are amended for clarification, including addressing the 35 U.S.C. §112 rejections. The amendments do not narrow the scope of the broadest scope of the claims. Claims 1-31 and 33-37 are now pending herein.

### **The Restriction Requirement**

Applicants reiterate their position that the non-elected claims are subject to rejoinder should the elected claims be found allowable. To bolster this assertion, claims 32-33 drawn to nebulizing methods, have been canceled. The remaining non-elected claims are all directed to compositions ultimately dependent on claim 1 and fully within the scope of claim 1. A finding of allowability of claim 1 would necessitate allowability (over the prior art) of these composition claims. These claims have also been reviewed and amended to address any informalities or potential 35 U.S.C. §112 issues.

### **The Rejections under 35 U.S.C. §112**

The rejection of claim 37 under 35 U.S.C. §112, first paragraph, is believed to be overcome by the amendment thereto whereby it is amended analogously to claim 35, as suggested in the Office Action.

The rejection of claims 4 and 5 under 35 U.S.C. §112, second paragraph, is believed to be rendered moot, at least in part, by the amendment to claim 4. The parenthetical recitation is removed from claim 4 and it is noted that there was no parenthetical recitation in claim 5. As to the use of differing types of nomenclature to identify the particular NK<sub>1</sub> receptor antagonists, applicants respectfully submit that such does not render the claims

indefinite. One of ordinary skill in the art would readily recognize the definite meaning of the terms used in these claims, given that they are identified as being particular NK<sub>1</sub> antagonists. Uniform nomenclature is not always used in the relevant field and such is not required by 35 U.S.C. §112, second paragraph. Whether defined by alphanumeric code, generic name, chemical name or chemical formula, to those of skill in this art the meaning would be clear. Thus, it is believed that 35 U.S.C. §112, second paragraph, is satisfied.

**The Obviousness-type Double Patenting Rejection over Eickmeier in view of Pieper**

The obviousness-type double patenting rejection of claims 1-8 and 36 over claims 13-18 of Eickmeier (U.S. Patent No. 6,696,462) in view of Pieper (U.S. Pub. No. 2006/0183726) is respectfully traversed.

Applicants respectfully submit that the instantly claimed invention is not an obvious variant of the claimed invention of the patent.

Applicants' invention (of claim 1) is directed to a combination of an anticholinergic compound of formula 1 with an NK<sub>1</sub> receptor antagonist compound. The claims of the patent recite a compound of a general formula which does not disclose or even encompass a compound of the claimed formula 1. As recognized in the Office Action the Eickmeier compounds are distinct in structure at least due to a cyclopropyl group in place of the epoxy group in formula 1 of the instant claims. Eickmeier gives no suggestion of claims encompassing applicants' formula 1. There is also no proper basis to assert that applicants' formula 1 compounds are equivalent to the cyclopropyl compounds of Eickmeier.

The secondary reference of Pieper is not prior art and cannot be relied upon for a teaching of equivalence. A secondary reference cited to support an obviousness-type double patenting rejection must be available as prior art under 35 U.S.C. §103. Pieper was filed in

Feb. 2006 and is not available as prior art for obviousness purposes against the instant application. The corresponding EP application of Pieper is also not available as prior art. In any event, Pieper does not suggest equivalency of compounds with the cyclopropyl structure to compounds with the epoxy structure. Although Pieper encompasses both in its generic formula, there is no statement that they are equivalent. However, this is irrelevant because Pieper cannot be relied upon.

For the above reasons alone, the obviousness-type double patenting rejection should be withdrawn.

Additionally, there are no claims in Eickmeier which recite or suggest the combination of an NK<sub>1</sub> receptor antagonist with the anticholinergic. Further, one of ordinary skill in the art reading the specification of the patent would not be directed to select an NK<sub>1</sub> receptor antagonist to combine with the anticholinergic. Eickmeier recites combining an anti-allergic and it is alleged that Saredutant falls within the definition of an anti-allergic and would also be an NK<sub>1</sub> receptor antagonist. Applicants note that their claims and specification included Saredutant in the list of NK<sub>1</sub> receptor antagonists. In fact, Saredutant is not an NK<sub>1</sub> receptor antagonist but, rather, a NK<sub>2</sub> antagonist (see attached excerpt from Wikipedia). The specification and claims have been amended to correct this error.

For all of the above reasons, the facts do not support that applicants are seeking two patents on the same invention or a substantially similar invention. Thus, the obviousness-type double patenting rejection should be withdrawn.

#### **The Obviousness-type Double Patenting Rejection over Pairet in view of Pieper**

The obviousness-type double patenting rejection of claims 1-8 and 35-37 over claims 1-12 of Pairet (U.S. Patent No. 6,696,042) in view of Pieper (U.S. Pub. No. 2006/0183726) is

respectfully traversed.

The reasons given above for traversing the obviousness-type double patenting rejection over Eickmeier in view of Pieper apply at least as strongly to this rejection and are incorporated by reference. The case is even stronger here because Pairet does not encompass the use of anticholinergics which are disclosed in either of applicants formula 1 or the disclosure of Pieper. The compound disclosed at page 4, paragraph [0106], of Pieper is not tiotropium encompassed within Pairet, as alleged in the Office Action. In any event, this is irrelevant because, for the reasons stated above, Pieper cannot be relied upon as a secondary reference to support this rejection.

For all of the above reasons, the facts do not support that applicants are seeking two patents on the same invention or a substantially similar invention. Thus, the obviousness-type double patenting rejection should be withdrawn.

#### **The Obviousness-type Double Patenting Rejection over Meissner**

The obviousness-type double patenting rejection of claims 1-8 and 36 over claim 9 of Meissner (U.S. Patent No. 6,706,726) is respectfully traversed.

Applicants respectfully submit that the instantly claimed invention is not an obvious variant of the claimed invention of the patent.

There are no claims in Meissner which recite or suggest the combination of an NK<sub>1</sub> receptor antagonist with the anticholinergic. Further, one of ordinary skill in the art reading the specification of the patent would not be directed to select an NK<sub>1</sub> receptor antagonist to combine with the anticholinergic. Meissner recites combining an anti-allergic and it is alleged that Saredutant falls within the definition of an anti-allergic and would also be an NK<sub>1</sub> receptor antagonist. Applicants note that their claims and specification included

Saredutant in the list of NK<sub>1</sub> receptor antagonists. In fact, Saredutant is not an NK<sub>1</sub> receptor antagonist but, rather, a NK<sub>2</sub> antagonist (see attached excerpt from Wikipedia). The specification and claims have been amended to correct this error.

For all of the above reasons, the facts do not support that applicants are seeking two patents on the same invention or a substantially similar invention. Thus, the obviousness-type double patenting rejection should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

Respectfully submitted,

/John A. Sopp/

John A. Sopp, Reg. No. 33,103  
Attorney for Applicants

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

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